IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

PLANNED PARENTHOOD OF GREATER TEXAS SURGICAL HEALTH SERVICES, PLANNED PARENTHOOD CENTER FOR CHOICE, PLANNED PARENTHOOD SEXUAL HEALTHCARE SERVICES, PLANNED PARENTHOOD WOMEN'S HEALTH CENTER, WHOLE WOMAN'S HEALTH, AUSTIN WOMEN'S HEALTH CENTER KILLEEN HEALTH CENTER, SOUTHWESTERN WOMEN'S SURGERY CENTER, WEST SIDE CLINIC, INC., ROUTH STREET WOMEN'S CLINIC, HOUSTON WOMEN'S CLINIC, EACH ON BEHALF OF ITSELF, ITS PATIENTS AND PHYSICIANS, ALAN BRAID, M.D., LAMAR ROBINSON, M.D., PAMELA J. RICHTER, D.O., EACH ON BEHALF OF THEMSELVES AND THEIR PATIENTS, PLAINTIFFS,	§	
V.	§	CAUSE NO. 1:13-CV-862-LY
GREGORY ABBOTT, ATTORNEY GENERAL OF TEXAS; DAVID LAKEY, M.D., COMMISSIONER OF THE TEXAS DEPARTMENT OF STATE HEALTH SERVICES; AND MARI ROBINSON, EXECUTIVE DIRECTOR OF THE TEXAS MEDICAL BOARD, DEFENDANTS.	§	

MEMORANDUM OPINION
INCORPORATING FINDINGS OF FACT AND CONCLUSIONS OF LAW

The Second Called Session of the 83rd Texas Legislature passed "[an act] relating to the regulation of abortion procedures, providers, and facilities [and] providing penalties." Act of July 12, 2013, 83rd Leg., 2d C.S., ch. 1, §§ 1-12, 2013 Tex. Sess. Law Serv. 4795-4802 (to be codified at Tex. Health & Safety Code §§ 171.0031, 171.041-048, 171.061-064, & amending §§ 245.010-

.011; Tex. Occ. Code amending §§ 164.052 & 164.055) ("House Bill 2" or the "act"). The Texas Governor approved the act, and, as pertinent here, the act takes effect October 29, 2013.

Plaintiffs Planned Parenthood of Greater Texas Surgical Health Services, Planned Parenthood Center for Choice, Planned Parenthood Sexual Healthcare Services, Planned Parenthood Women's Health Center, Whole Woman's Health, Austin Women's Health, Austin Women's Health Center, Killeen Women's Health Center, Southwestern Women's Surgery Center, West Side Clinic, Inc., Routh Street Women's Clinic, Houston Women's Clinic, Alan Braid, M.D., Lamar Robinson, M.D., and Pamela Richter, D.O., all providers of abortion services, bring this action on behalf of themselves, their physicians, and their patients, complaining that certain provisions of the act should be declared unconstitutional.[1]

Planned Parenthood also seeks a permanent injunction, enjoining Gregory Abbott, Attorney General of Texas, David Lakey, M.D., Commissioner of the Texas Department of State Health Services, and Mari Robinson, Executive Director of the Texas Medical Board (collectively, the "State"), from enforcing those provisions of the act.[2]

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[1] Because the interests of Plaintiffs do not diverge, the court will refer to them collectively as "Planned Parenthood."

[2] Planned Parenthood also originally sued David Escamilla, County Attorney for Travis County, Craig Watkins, Criminal District Attorney for Dallas County, Devon Anderson, District Attorney for Harris County, Matthew Powell, Director of the Lubbock County Criminal District Attorney's Office, James E. Nichols, County Attorney for Bell County, Joe Shannon, Jr., Criminal District Attorney for Tarrant County, René Guerra, Criminal District Attorney for Hidalgo County, Susan D. Reed, Criminal District Attorney for Bexar County, Abelino Reyna, Criminal District Attorney for El Paso County, and Jaime Esparza, District Attorney for El Paso County, each in their official capacities, as well as their employees, agents, and successors, seeking the same injunction relief as against the State. Upon the stipulation of the parties, the court dismissed these Defendants. *Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott*, No. 1-13CV862-LY (W.D. Tex. Oct. 18, 2013).

Planned Parenthood asserts that two provisions of the act fail constitutional review and must be held unenforceable–those that mandate that a physician performing or inducing an abortion "must, on the date the abortion is performed or induced, have active admitting privileges at a hospital that is not further than 30 miles from the location of the abortion" and those that place restrictions on medication abortions.

Today there is no issue that divides the people of this country more than abortion. It is the most divisive issue to face this country since slavery. When compared with the intensity, emotion, and depth of feeling expressed with regard to abortion, the recent arguments on affordable healthcare, increasing the debt ceiling, and closing the government retreat to near oblivion. Sincere and caring persons of good will are found on both sides of the issue, but neither side will ever change the position of the other. Legislatures and courts will continue to be confounded by the issue for the foreseeable future. No ruling of this court will sway the opinion regarding abortion held by anyone. And, indeed, that is not the role of this court. The court may not and will not decide whether there should be abortions in Texas. This court is charged only with determining whether certain provisions of House Bill 2 are consistent with the Constitution of the United States under existing Supreme Court precedent.

Although the Texas Legislature passed House Bill 2 July 12 and had debated the act at length during the legislature's First Called Session, thus making the act's provisions well known, Planned Parenthood waited until September 26 to challenge the act. Due to the importance of the issues and the public interest in the act, and because the challenged provisions of House Bill 2 take effect October 29, this court determined to dispense with hearing Planned Parenthood's request for a

preliminary injunction and consolidated that request with trial on the merits. Fed. R. Civ. P. 65(a)(2). The parties in open court waived a jury trial.

Three established principles govern this court's consideration of House Bill 2: (1) Before fetal viability, a woman has a right to terminate her pregnancy. (2) A law designed to further the State's interest in fetal life which imposes an undue burden on a woman's decision before fetal viability is unconstitutional. A state regulation that has the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus is an undue burden. (3) After fetal viability, the State, in promoting its interest in the potentiality of human life, may regulate or proscribe abortion, except where it is necessary for the preservation of the life or health of the mother. *Stenberg v. Carhart*, 530 U.S. 914, 921 (2000) (internal citations and quotations omitted) (citing *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 879 (1992); *Roe v. Wade*, 410 U.S. 113, 164-65 (1973)).

Having carefully considered the parties' briefing, stipulations, exhibits, trial testimony, arguments of counsel, and the applicable law[3], the court concludes: (1) the act's admitting-privileges provision is without a rational basis and places a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus, and (2) the act's provisions that place restrictions on medication

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[3] The court denied the parties' objections to the use of declarations at trial, but allowed the parties to file specific objections to the other's declarations. Pending are Planned Parenthood's Plaintiffs' Objections to Defendants' Evidence and the State's Evidentiary Objections to Plaintiff's Declarations and Rebuttal Declarations, both filed October 22, 2013. The court overrules Planned Parenthood and the State's objections. The declarations have equivalent circumstantial guarantees of trustworthiness, are offered as evidence of one or more material facts, are more probative of the point for which offered than any other evidence that the parties can obtain through reasonable efforts, particularly in light of the acceleration of trial of this case, and admitting the declarations will best serve the rules of evidence and the interests of justice. FED. R. EVID. 807. In reaching these findings and conclusions, the court relies only upon admissible evidence.

abortions do not place such an obstacle, except when a physician finds such an abortion necessary, in appropriate medical judgment, for the preservation of the life or health of the mother. In so deciding, the court makes the following findings of fact and conclusions of law.[4]

I. STANDING

At the threshold, the State challenges Planned Parenthood's standing to bring this action. "[T]he term standing subsumes a blend of constitutional requirements and prudential considerations." *Valley Forge Christian Coll. v. Americans United for Separation of Church & State, Inc.*, 454 U.S. 464, 471 (1982). To meet the constitutional requirements, a plaintiff must have suffered an injury in fact caused by the challenged government conduct and likely to be redressed by the relief sought. *See Lujan v. Defenders of Wildlife,* 504 U.S. 555, 560-61 (1992). In addition to the constitutional requirements, the Supreme Court also has applied certain prudential principles in determining whether litigants have standing. *Valley Forge Christian Coll.*, 454 U.S. at 474-75; *see also Apache Bend Apartments, Ltd. v. United States,* 987 F.2d 1174, 1176 (5th Cir. 1993). A plaintiff must assert his legal rights and interests, and his complaint must fall within "the zone of interests" to be protected or regulated by the statute or constitutional guarantee in question. *Valley Forge Christian Coll.*, 454 U.S. at 474-75.

The Supreme Court has consistently reviewed the substance of constitutional challenges to abortion-related statutes without specifically addressing a plaintiff's standing. *See, e.g., Gonzales*

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[4] In making the following findings of fact and conclusions of law, the court has considered the record as a whole. The court has observed the demeanor of the witnesses and has carefully weighed that demeanor and the witnesses' credibility in determining the facts of this case and drawing conclusions from those facts. All findings of fact contained herein that are more appropriately considered conclusions of law are to be so deemed. Likewise, any conclusion of law more appropriately considered a finding of fact shall be so deemed.

v. Carhart, 550 U.S. 124 (2007); *Stenberg v. Carhart*, 530 U.S. 914 (2000); *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833 (1992). That abortion providers may raise constitutional challenges to state statutes that seek to regulate abortions is now so well established in our jurisprudence it is axiomatic.

The court concludes that Planned Parenthood has standing to assert the claims alleged in this action.

II. ADMITTING PRIVILEGES

Planned Parenthood attacks certain provisions of Section 2 of the act, which assess a criminal penalty against a physician performing an abortion who does not have certain hospital admitting privileges. Section 2 would amend the Texas Health & Safety Code to provide a new Section 171.0031. Although pleaded somewhat generally, the court construes Planned Parenthood to assert that the proposed code provision Section 171.0031 (a)(1) fails constitutional review. The provision provides that a physician performing or inducing an abortion:

> (1) must, on the date the abortion is performed or induced, have active admitting privileges at a hospital that:
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> (A) is located not further than 30 miles from the location at which the abortion is performed or induced; and
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> (B) provides obstetrical or gynecological health care services . . . .

Planned Parenthood also objects to proposed Section 171.0031 (b) to the extent that it criminalizes a physician's failure to comply with Section 171.0031 (a)(1):

> (b) A physician who violates Subsection (a) commits an offense. An offense under this section is a Class A

> misdemeanor punishable by a fine only, not to exceed $4,000.[5]

(together "admitting privileges").

"Before viability, a State, may not prohibit any woman from making the ultimate decision to terminate her pregnancy." *Gonzales*, 550 U.S. at 146 (quoting *Casey*, 505 U.S. at 879). "[The State] also may not impose upon this right an undue burden, which exists if a regulation's 'purpose or effect is to place a substantial obstacle in the path of a woman seeking an abortion before the fetus attains viability.'" *Id.* On the other hand, "[r]egulations which do no more than create a structural mechanism by which the State . . . may express profound respect for the life of the unborn are permitted, if they are not a substantial obstacle to the woman's exercise of the right to choose." *Id.* "*Casey*, in short struck a balance." *Id.* (citing *Casey*, 505 U.S. at 877). The court is guided by these particular statements in addressing Planned Parenthood's allegations.

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[5] Proposed Section 171.0031 (a) (2) requires a physician performing or inducing an abortion to provide the pregnant woman with information to assist her in reaching the physician and the facility in which she was treated to obtain her medical records, obtain assistance for complications arising from the abortion, and to ask health-related questions regarding the abortion. The section also requires the physician to provide the woman with the name and telephone number of the hospital nearest the woman's home which would treat her for an emergency arising from the abortion. Planned Parenthood does not appear to object to this provision. To the extent that it does, the court concludes that the provision does not constitute an undue burden on a woman's right to seek a previability abortion.

Under the undue-burden test, courts proceed with a two-pronged inquiry.[6] First, courts must subject regulations to a rational-basis review to determine whether the law's purpose or effect is rationally related to the state's legitimate interest balanced with the woman's interest.[7] *See, e.g., Stenberg*, 530 U.S. at 914; *Casey*, 505 U.S. at 876-77, 882, 885 (not limiting itself to inquiry into whether state's interest was legitimate or its purpose permissible; noting that provisions were reasonable means of "furthering" approved interest; stating "in our view, the undue burden standard is the appropriate means of reconciling the State's interest with the woman's constitutionally protected liberty"); *Gonzales*, 550 U.S. at 158 (reciting *Casey*'s purpose or effect test: "Where it has a rational basis to act, *and* it does not impose an undue burden, the State may use its regulatory powers to bar certain procedures and substitute others, all in furtherance of its legitimate interests in regulating the medical profession in order to promote respect for life, including life of the unborn.").

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[6] Circuit courts have also applied the undue-burden standard when evaluating abortion regulations. *See, e.g. Victoria W. v. Larpenter*, 369 F.3d 475 (5th Cir. 2004) (finding nexus between policy and government's interest); *Tucson Woman's Clinic v. Eden*, 379 F.3d 531 (9th Cir. 2004) (whether state's ends are reasonably furthered by its means); *Planned Parenthood of Wis. v. Doyle*, 162 F.3d 463, 471 (7th Cir. 1998) (same); *Planned Parenthood of Greater Iowa, Inc. v. Atchison*, 126 F.3d 1042 (8th Cir. 1997) (invalidating state law requiring family planning clinics obtain certificates of need for new clinic construction, assessing whether law was "valid means of furthering a legitimate state interest").

[7] Supreme Court decisions implicitly show that lower courts' inquiries begin with whether challenged legislation was a "permissible means of serving" the state's legitimate purpose before reaching the second prong of the undue burden analysis. The Court's emphasis on lower courts' need to evaluate how a statute furthers and serves a state's interest militate a nexus inquiry. For example, the Court noted that "a statute which, while furthering the interest in potential life or some other valid state interest, has the effect of placing a substantial obstacle in the path of a woman's choice cannot be considered a permissible means of serving its legitimate ends." *Casey*, 505 U.S. at 877; *also see id.* at 878 (unless there is substantial obstacle, "a state measure designed to persuade [a woman] to choose childbirth over abortion will be upheld if reasonably related to that goal."

If a law survives the first prong, the court must proceed to analyze it under the second prong. *Casey*, 505 U.S. at 877 (determining whether law places "substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus."). The "purpose" inquiry is an assessment of the legislature's real purpose. The appropriate analysis is whether the state's purpose is to hinder autonomous reproductive choice, distinct from a rational-basis analysis. *See Casey*, 505 U.S. at 878 (requiring that regulation be motivated by permissible "purpose"). The court's evaluation of the law's "effects" assess whether the regulation places a "substantial obstacle" before a woman seeking abortion services. *Id.* Under this inquiry, regulations imposing an "undue burden" on women seeking previability abortion services are unconstitutional. *Id.* at 878-79.

Planned Parenthood argues that the admitting privileges impose an undue burden on patients, are unconstitutionally vague,[8] violate the procedural-due-process rights of physicians, and unlawfully delegate authority to hospitals to determine who may perform abortions.

The State argues that when an abortion provider has privileges at a local hospital, the provider is more likely to effectively manage patient complications by providing continuity of care and decreasing the likelihood of medical errors. The State points to evidence that 80% of significant negative outcomes at emergency rooms relate to difficulties with physician communication and

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[8] Planned Parenthood claims that the admitting privileges provision fails to define the meaning of "active admitting privileges" and therefore it fails to give Planned Parenthood fair notice of the requirements of the act and leaves physicians subject to arbitrary and discriminatory enforcement. The court finds that the wording of the admitting-privileges provision provides physicians of ordinary intelligence a reasonable opportunity to know what is prohibited, sets forth relatively clear guidelines as to prohibited conduct, and provides objective criteria of what is required. *See Gonzales*, 550 U.S. at 149. Active admitting privileges means just that, and the court finds that a physician of ordinary intelligence would recognize and understand the difference, and therefore concludes the admitting-privileges section of House Bill 2 is not unconstitutionally vague.

patient handoff. The State however, provides no evidence of correlation between admitting privileges and improved communication with patient handoff or that a communication problem actually exists between abortion providers and emergency-room physicians.

A lack of admitting privileges on the part of an abortion provider is of no consequence when a patient presents at a hospital emergency room. By law, no hospital can refuse to provide emergency care. *See* 42 U.S.C. § 1395dd. The evidence reflects that emergency-room physicians treat patients of physicians with admitting privileges no differently than patients of physicians without admitting privileges. Admitting privileges make no difference in the quality of care received by an abortion patient in an emergency room, and abortion patients are treated the same as all other patients who present to an emergency room.

The court concludes that whether an abortion provider has admitting privileges does nothing to further the interest of patient care by improving communication. Nor does it impact the timeliness of care in the emergency room, where the nature of the practice is to treat patients with all possible haste.

The State also argues that admitting privileges address issues of patient abandonment, hospital costs, and accountability. There is however, no evidence that these concerns were assuaged by requiring abortion providers to have admitting privileges at a hospital within 30 miles of the clinic where they provide abortion services.

The court concludes that there is no rational relationship between improved patient outcomes and hospital admitting privileges within 30 miles of a facility in which a physician provides abortion services.

The State also argues that an abortion provider having admitting privileges would improve treatment, once an abortion patient is at the hospital. The State points to abortion's unique potential for danger and purports to address this danger by requiring admitting privileges. The court finds this argument unconvincing.

Jennifer Carnell, an emergency-room physician at Ben Taub Hospital in Houston, Texas, testified that she has never had an occasion to consider whether an incoming patient's physician has admitting privileges at the hospital. Additionally, she would not have treated any patient differently if she were aware of that fact.

The court concludes that admitting privileges have no rational relationship to improved patient care. Admitting privileges do not rationally relate to the State's legitimate interest in protecting the unborn. The court concludes that the hospital-admitting-privileges provision fails a rational-basis review.

Should there be a rational basis, however, the provision still fails, as the court also concludes that Planned Parenthood has met its burden of demonstrating that the hospital-admitting-privileges provision of the act places an "undue burden" on a woman seeking abortion services in Texas because it necessarily has the effect of presenting a "substantial obstacle" to access to abortion services. *Casey*, 505 U.S. at 878.

By requiring abortion providers to have hospital admitting privileges, the evidence is that there will be abortion clinics that will close. The record reflects that 24 counties in the Rio Grande Valley would be left with no abortion provider because those providers do not have admitting privileges and are unlikely to get them.

The State argues that at *some* point in the future *some* abortion providers *may* be granted admitting privileges and services at those clinics would return. However, under the act, in order to perform abortions, physicians without privileges must complete a hospital's application process for privileges, which undisputedly takes 90 to 170 days. The act has no tolling period. Each hospital's bylaws are unique, thereby causing variability in hospital-privilege application requirements, such as: physician residency, board certification, threshold number of surgical procedures, threshold numbers of annual hospital admissions, among others. Testimony from Amy Hagstrom-Miller, an owner of Whole Women's Health Services, explained her difficulties getting the current physicians at Whole Women's Health Services facilities in compliance with the act. Most of the physicians at her clinics are over 60-years-old and half are over 70. These physicians do not currently have admitting privileges and cannot gain admitting privileges for reasons including lack of a board-certification specialty, retirement, impact on their private practice, and residing too geographically remote from the hospitals that are 30 miles from the Whole Women's Health Services facilities. Also, there is evidence that if required by the hospital, the vast majority of abortion providers are unable to ever meet the threshold annual hospital admissions, because the nature of the physicians' low-risk abortion practice does not generally yield any hospital admissions. Clinic physicians are similarly unable or unlikely to meet the threshold surgery numbers because they simply do not perform the qualifying surgeries.

The State suggests that clinics find replacement physicians who either already have admitting privileges or who could meet hospital requirements. Contrary to the State's optimism, Hagstrom-Miller's experience shows that finding physicians with active admitting privileges is difficult because physicians' contracts often bar them from providing "moonlight" services as abortion

providers. Hagstrom-Miller approached clinic-referring physicians in an attempt to recruit them to provide abortion services and all of those physicians have declined her invitation either because the physician is concerned about negative impact on their private practice in some way, either financially or as a result of attention from antiabortion protestors, or because their private practice contract precludes even part-time or contract abortion work.

The State argues that the matter is not ripe for review because pending applications have not yet been formally denied. However, this does nothing to make the ultimate outcome less of a foregone conclusion, because a subsequent granting of privileges at some later date is meaningless if in the interim the clinic has closed or the physician has taken another position.

The State fails to show a valid purpose for requiring that abortion providers have hospital privileges within 30 miles of the clinic where they practice. Accordingly, the hospital-admitting provision does not survive the undue-burden "purpose" inquiry. The court finds that the hospital-admitting-privileges provision of the act fails both prongs of the undue-burden test with regard to any woman seeking an abortion previability, therefore, the court concludes that Planned Parenthood's facial challenge to this provision may be maintained and the provision is unconstitutional.[9]

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[9] Other federal courts' evaluation of similar laws in Alabama, Mississippi, and Wisconsin have reached similar conclusions. *See, e.g., Planned Parenthood Se., Inc. v. Bentley*, 2013 WL 3287109, at *7 (M.D. Ala. June 28, 2013) (granting temporary restraining order where admitting privileges requirement would close three of five clinics in Alabama); *accord Jackson Womens' Health Org. v. Currier*, No. 3:12-CV-436-DPJ-FKB, 2013 WL 162365, at *5 (S.D. Miss. Apr. 15, 2013) (granting preliminary injunction after finding undue burden when state's admitting privileges requirement would close only known abortion provider in Mississippi); *accord Planned Parenthood of Wis., Inc. v. Van Hollen*, 2013 WL 3989238, at *16 (W.D. Wis. July 8, 2013); *see also Tucson Woman's Clinic v. Eden*, 379 F.3d 531, 541 (9th Cir. 2004) ("A significant increase in the cost of abortion or [decrease in] the supply of abortion providers and clinics can, at some point, constitute a substantial obstacle to a significant number of women choosing an abortion.").

Planned Parenthood also claims that the admitting privileges provision violates the right to procedural due process guaranteed to Planned Parenthood because it deprives physicians of a constitutionally adequate opportunity to attempt to comply. Additionally, Planned Parenthood claims that the admitting privileges provision makes physicians' ability to perform abortions contingent on obtaining privileges at local hospitals, and thereby unconstitutionally allows a private entity to set criteria that physicians must meet in order to provide an abortion.

The court concludes that the legislature never intended for a physician to be allowed a reasonable time to obtain admitting privileges. That a physician had 91 days from the end of the legislative session in which House Bill 2 was enacted is sheer happenstance. But for the lack of a very few votes in each legislative house, the act would have taken effect immediately. *See* Act of July 12, 2013, 83rd Leg., 2d C.S., ch.1, § 12, 2013 Tex. Sess. Law Serv. 4802.[10]

The court expresses grave reservations about allowing a hodge podge of diverse medical committees and boards to determine, based solely on admitting privileges, which physicians may perform abortions.

The court need not and does not address these claims, however, as the admitting-privileges provision of House Bill 2 lacks a rational basis and places an undue burden on a woman seeking an abortion.

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[10] The act passed the Texas House of Representatives 96 to 49, with 1 present, not voting and the Texas Senate 19 to 11.

IV. MEDICATION ABORTION

A medication abortion, also known as and referred to in the act as a medical abortion, requires the administration of two different drugs: mifepristone and misoprostol. Mifepristone, also referred to by its trade names Mifeprex or RU-486, terminates a pregnancy by blocking progesterone, a naturally produced hormone that prepares the lining of the uterus for a fertilized egg and helps maintain pregnancy. Without progesterone, the pregnancy cannot continue and the lining of the uterus softens and breaks down, and the embryo detaches from the uterine lining. Approximately 24 to 48 hours after the woman takes mifepristone, she takes the second drug, misoprostol, also known as prostaglandin or Cytotec, which causes the uterus to contract and expel the embryo and other products of conception. This same combination of drugs is offered to a woman who has had a miscarriage with retained tissue. In such cases, the mifepristone/misoprostol combination serves as an alternative to surgical removal of tissue in a dilation and curettage, a form of surgical abortion.

The United States Food and Drug Administration ("FDA") approved mifepristone, for the purpose of medication abortion in 2000. The FDA imposes restrictions on the use, dosage, and administration of mifepristone and misoprostol on mifepristone's final printed label. These restrictions are based on a testing regimen developed in Europe in the 1980s and used during clinical trials. The restrictions and instructions on mifepristone's final printed label ("the FDA protocol")[11] include limiting the drug's use to the first 49 days following the woman's last menstrual period ("LMP"), setting conditions for administering both drugs to patients, prescribing dosage levels and route of administration, setting conditions about timing of patient visits, and listing requisite

[11] Referred to in the act as "Mifeprex regimen," "RU-486 regimen," and "RU-486." *See* Act of July 12, 2013, 83rd Leg., 2d C.S., ch.1, § 3, 2013 Tex. Sess. Law Serv. 4798.

qualifications of prescribing physicians. The FDA does not test medications, but reviews studies resulting from the clinical trials performed by the drug manufacturer. In the case of mifepristone, the clinical trials involved fewer than 3000 women. Although previously prescribed extensively in other countries, mifepristone went into wide use in the United States only after FDA approval.

Abortion-performing physicians have since developed a medication-abortion protocol using mifepristone that, although varying significantly from the FDA protocol, has become the *de facto* standard of care in Texas.[12] This protocol, or one substantially identical, accounts for the vast majority of medication abortions performed nationwide since 2007. The new protocol, endorsed by the American College of Obstetricians and Gynecologists ("the off-label protocol") prescribes mifepristone to be taken at the clinic in a significantly lower dosage than the FDA protocol, changes the misoprostol administration route to buccal (holding the drug tablet between the gum and cheek),[13] lowers the misoprostol dosage, adds an antibiotic regimen to combat sepsis complications, and allows for at-home administration of the misoprostol. At-home administration is important because the drug, taken buccally, triggers almost immediate bleeding and cramping. A woman, therefore, may prefer the privacy and comfort of her home when administering misoprostol. In addition, the off-label protocol requires a woman to make two trips to see her physician and

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[12] The practice of developing new protocols using different dosages or using medications for different uses than for which they were approved by the FDA is not unique to mifepristone. It is common in medicine, when supported by adequate study, to use and prescribe medication in this "off-label" use. Misoprostol, for example, was originally approved by the FDA as a drug used to reduce the incidence of gastric ulcers in patients taking anti-inflammatory drugs and is labeled for that use. However, in addition to being used as a part of medical-abortion protocols, it is also used in obstetrics to ripen the cervix prior to the induction of labor and to stop postpartum hemorrhage.

[13] The FDA protocol calls for oral administration, and an alternate protocol, not discussed further in this opinion, calls for vaginal administration of the misoprostol.

occasionally only one.[14] In contrast, the FDA protocol requires three separate visits to the clinic: one for the administration of mifepristone, one for the administration of the misoprostol, and one for a follow-up to ensure the pregnancy was successfully terminated. Based on efficacy research, the off-label protocol also extends the window that mifepristone can be safely and reliably used for a medication abortion to up to 63 days LMP. Since mifepristone was approved by the FDA, over 1.75 million women have had medication abortions. Nothing in the record indicates that any deaths have been reported in conjunction with the off-label protocol.[15]

Section 3 of House Bill 2 amends the Texas Health & Safety Code to provide a new Section 171.063. Although pleaded somewhat generally, the court construes Planned Parenthood to assert that portions of proposed Section 171.063 fail constitutional review. Those provisions, subsections (a)(2), (b), (c), (e), and (f), provide that a physician performing or inducing an abortion:

> (a) [ ] may not knowingly give, sell, dispense, administer, provide or prescribe an abortion-inducing drug to a pregnant woman for the purpose of inducing an abortion in the pregnant woman or enabling another person to induce an abortion in the pregnant woman unless:
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> . . . .

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[14] Testimony at trial showed that in a normal administration, the physician gives the misoprostol dose to the patient for at-home use. Then, after the induced miscarriage is complete, the patient returns to the clinic for a follow-up to verify the success of the abortion. For some patients for whom travel is a burden, the "follow-up visit" may be satisfied by a blood test at a location more convenient than the abortion clinic in order to determine that the pregnancy is terminated.

[15] Both parties rely on an FDA study that concludes that there have been eight deaths associated with medication abortion since the approval of mifepristone. The record does not establish that these eight deaths were conclusively connected to a particular protocol. The FDA studied the deaths and concluded that it "do[es] not know whether using mifepristone and misoprostol caused these deaths" and has not suggested that an alternative regimen was to blame. *See* Mifeprex Questions and Answers (Feb. 24, 2010) (available at http://www.fda.gov/Drugs/DrugSafety/Post-marketDrugSafetyInformationforPatientsandProviders/ucm111328.htm).

> (2) except as otherwise provided by Subsection (b), the provision, prescription, or administration of the abortion-inducing drug satisfies the protocol tested and authorized by the United States Food and Drug Administration as outlined in the final printed label of the abortion-inducing drug.

(b) A person may provide, prescribe, or administer the abortion-inducing drug in the dosage amount prescribed by the clinical management guidelines defined by the American Congress of Obstetricians and Gynecologists Practice Bulletin as those guidelines existed on January 1, 2013.

(c) Before the physician gives, sells, dispenses, administers, provides, or prescribes an abortion-inducing drug, the physician must examine the pregnant woman and document, in the woman's medical record, the gestational age and intrauterine location of the pregnancy.

. . . .

(e) The physician who gives, sells, dispenses, administers, provides, or prescribes an abortion-inducing drug, or the physician's agent, must schedule a follow-up visit for the woman to occur not more than 14 days after the administration or use of the drug. At the follow-up visit, the physician must:

> (1) confirm that the pregnancy is completely terminated; and
>
> (2) assess the degree of bleeding.

(f) The physician who gives, sells, dispenses, administers, provides, or prescribes an abortion-inducing drug, or the physician's agent, shall make a reasonable effort to ensure that the woman returns for the scheduled follow-up visit under Subsection (e). The physician or the physician's agent shall document a brief description of any effort made to comply with this subsection, including the date, time, and name of the person making the effort, in the woman's medical record.

Planned Parenthood also objects to proposed Section 171.064 to the extent that it punishes a physician's failure to comply with Section 171.063:

> (a) The Texas Medical Board may take disciplinary action under Chapter 164, Occupations Code, or assess an administrative penalty under Subchapter A, Chapter 165, Occupations Code, against a person who violates Section 171.063.[16]

(together "medication-abortion provisions").

Thus, House Bill 2 restricts the use of abortion-inducing drugs to the FDA protocol, with one exception: it allows a physician to prescribe the *dosage* recommended in the clinical management guidelines defined by the American Congress of Obstetricians and Gynecologists Practice Bulletin as those guidelines existed on January 1, 2013. The protocol described in the Practice Bulletin is roughly analogous to the off-label protocol, but the act clearly does not allow the physician to follow the *administration* or *route* portions of the off-label protocol.[17] Each party concedes that an off-label

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[16] Proposed Section 171.063 (a) (1) requires the person performing or inducing an abortion to be a physician. Proposed Section 171.063 (d) requires the physician performing or inducing an abortion to provide the pregnant woman with information from the final printed label of that abortion-inducing drug and to assist her in reaching the physician and the facility in which she was treated to obtain her medical records, obtain assistance for complications arising from the abortion, and to ask health-related questions regarding the abortion. Proposed Section 171.063 (g) also requires that, if the physician knows that the woman experiences a serious adverse event as defined by the MedWatch Reporting System during or after the administration or use of the drug, the physician shall report the event to the FDA through the MedWatch Reporting System not later than the third day after the date the physician learns that the event occurred. Planned Parenthood does not appear to object to these provisions. To the extent that it does, the court concludes that the provisions do not constitute an undue burden on a woman's right to seek an abortion of a nonviable fetus.

[17] Planned Parenthood brings a vagueness challenge based upon the language in Section 171.063(b). The court finds that the wording of 171.063(b) "provides doctors of ordinary intelligence a reasonable opportunity to know what is prohibited[,] ... sets forth relatively clear guidelines as to prohibited conduct[,] and provides objective criteria to evaluate whether a doctor has performed a prohibited procedure." *Gonzales*, 550 U.S. at 149 (internal quotation marks omitted)

protocol-based dosage of mifepristone taken out of the context of the rest of the protocol is untested, may lead to unpredictable results, and is unlikely an acceptable standard of care.

Planned Parenthood contends that the FDA protocol mandated by House Bill 2 is not medically necessary and that the off-label protocol, taken as a whole, is the safest, mostly widely used, and medically appropriate use of mifepristone. Planned Parenthood asserts that the FDA protocol is not as effective, is more dangerous, and has more severe complications and side effects than the off-label protocol. Under the FDA protocol, the unavailability of medical abortion from 50 to 63 days LMP is particularly problematic, Planned Parenthood states, for women with physical conditions that contraindicate surgical abortion or for those of whom surgical abortion is more dangerous.[18] Planned Parenthood's argument is that, by restricting women's access to a preferred

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(citing *Grayned v. City of Rockford,* 408 U.S. 104, 108 (1972); *Posters 'N' Things,* 511 U.S. 513, 525–526). Dosage means dosage, not dosage *and* administration route *and* protocol, and the court finds that a physician of ordinary intelligence would recognize and understand the difference, and therefore concludes that the medication-abortion section of House Bill 2 is not unconstitutionally vague.

[18] Planned Parenthood provides uncontroverted evidence that some women have medical conditions that can make first-trimester surgical abortion extremely difficult or impossible. Such cases may include women who are extremely obese, have uterine fibroids distorting normal anatomy, have a uterus that is very flexed, or have certain uterine anomalies. For these women, surgical abortion poses much higher risks of failed abortion, as well as complications such as perforation of the uterus. Another circumstance where surgical abortion may be higher risk is when a woman has a condition known as stenotic cervix–a cervix with an abnormally small opening, often caused by scarring from prior surgeries. It may also happen when a woman has undergone female genital mutilation. Requiring a woman with these conditions to have surgical rather than medication abortion may put them at significantly higher risk for damage to the cervix or other complications, including uterine perforation. The State presents evidence that the risk of incomplete medical abortion contraindicates medical abortion for the class of women with anatomical risk factors, as a surgical abortion may be required to complete an unsuccessful medical abortion. In light of the relatively low rate of unsuccessful medical abortions, this court finds the State's evidence on this matter unconvincing.

and arguably safer method of abortion and eliminating it's availability from 50 to 63 days LMP, the law is unduly burdensome.

The State counters that the FDA protocol, by virtue of its FDA imprimatur, is necessarily a sound, medically approved method and as such cannot impose an undue burden on women. It is a safe method of using the drug, the State argues, and that should end the inquiry. Moreover, the State reasons, surgical abortion remains a safe and common alternative for the entire period during which a medication abortion might be elected, including days 50 to 63 LMP where medical abortion would be unavailable. According to the State, the additional visit to the clinic and the additional safeguards in the FDA protocol provide an increase overall patient safety by increasing physician-patient contact during the medication-abortion process.

This court finds that, when performed in accordance with the off-label protocol, medication abortion is a safe and effective procedure, as is medication abortion with the FDA protocol. The variable risk of a significant adverse event is so low it becomes hard to quantify. Reliable data on medication abortions following solely the FDA protocol is sparse, as physicians overwhelmingly moved away from the FDA protocol soon after it was approved. However, as can be seen in the opposing declarations of Dr. Paul Fine and Dr. Donna Harrison, as well as Dr. Fine's testimony at trial, reasonable medical opinion on the overall safety, efficacy, and preferability of the protocols may differ.

Moreover, the court finds that the FDA protocol is assuredly more imposing and unpleasant for the woman, requiring at least one additional visit to a clinic and allowing less control over the timing and convenience of the medically induced miscarriage. It also requires more of the

physician's time, as the physician must administer the second dose.[19] The FDA protocol is also marginally more expensive, due to the increased dosage, notwithstanding any additional cost of travel, time off of work, and childcare. Most importantly, the FDA protocol removes medication abortion as an option for any woman who discovers she is pregnant or decides to terminate a pregnancy after 49 days LMP.[20] Taken as a whole, the FDA protocol is clearly more burdensome to a woman than the off-label protocol.

Regarding the likelihood of the additional visit to the physician required by the FDA protocol, the additional discomfort and inconvenience visited upon a woman, and the additional cost imposed by the higher dose of mifepristone, the law is clear: "[T]he incidental effect of making it more difficult or more expensive to procure an abortion cannot be enough to invalidate" a law. *Casey*, 505 U.S. at 874. In addition,

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[19] The FDA protocol does not require the physician to observe the patient take dose of misoprostol, or for the patient to remain at the clinic to take the drug or wait while the miscarriage occurs.

[20] Although specific numbers were not adduced at trial, the court finds that it is possible that a sizeable fraction of women may discover pregnancy or elect abortion during the period from 50 to 63 days LMP. For example, if a woman has a regular menstrual cycle and were to become pregnant, her first missed menstruation would come at 28 days LMP. If a woman's cycle is less than predictable, a missed menstruation may not be realized until 35 or even 42 days LMP. Even the most attentive woman may miss the exact calculation of her last menstruation and not take immediate proactive steps to determine if she is pregnant or merely irregular. Assuming a few days allowance for irregularity, a few days to process or explore the reality that she may be pregnant, a few days to schedule an appointment with an abortion provider, and, in some cases, an extra day for Texas's mandated 24-hour waiting period, a reasonably attentive woman could be edging dangerously close to the 49 day LMP limit on medication abortion provided by the FDA protocol.

> [n]umerous forms of state regulation might have the incidental effect of increasing the cost or decreasing the availability of medical care, whether for abortion or any other medical procedure. The fact that a law which serves a valid purpose, one not designed to strike at the right itself, has the incidental effect of making it more difficult or more expensive to procure an abortion cannot be enough to invalidate it.

Id. At some point, the totality of incidental effects may become an undue burden. However, the record before the court, when viewed through the prism of the Supreme Court's controlling precedent, establishes that threshold has not been met.

Most importantly, when "reasonable alternative procedure[s]" exist, the government's broad discretion to regulate medical practice allows regulation even if it means subjugating physician- or patient-preference. *Gonzales*, 550 U.S. at 163. Individuals do not have a constitutional right to a preferred medical option, so long as a safe, medically accepted, and actual alternative exists. *Id.* ("Physicians are not entitled to ignore regulations that direct them to use reasonable alternative procedures. The law need not give abortion doctors unfettered choice in the course of their medical practice."). Here, ample evidence establishes that a reasonable, safe, relatively inexpensive, and effective alternative exists for most women seeking a medical abortion before 63 days LMP, and for whom the FDA protocol makes medical abortion unavailable: a surgical abortion. In sum, as applied to most women, House Bill 2's restrictions on medication abortion do not rise to the level of an undue burden on the right to seek a previability abortion.

On the other hand, the court finds that there are certain situations where medication abortion is the only safe and medically sound option for women with particular physical abnormalities or

preexisting conditions.[21] At trial, the State represented that it would not prosecute a physician who violates the provisions of House Bill 2, if that physician provides a medication abortion to a woman whose life or health is endangered by the pregnancy or possibility of a surgical abortion. However, a promise not to prosecute from the Attorney General is not binding. This court cannot accept "as authoritative, an Attorney General's interpretation of state law when the Attorney General does not bind the state courts or local law enforcement authorities." *Stenberg*, 530 U.S. at 940 (internal quotations and citations omitted). House Bill 2's medication-abortion restriction places a substantial obstacle in the path of a woman seeking an abortion for whom surgical abortion is not a medically sound or safe option; thus, is not "a permissible means of serving [a] legitimate end []." *Casey*, 505 U.S. at 877; *see also Akron*, 462 U.S. 438. In the case of a woman for whom surgical abortion represents a significant health risk due to a physical condition beyond her control, the medication-abortion restrictions contained in House Bill 2 act as a total method ban after 49 days LMP. This court need not find alternative abortion procedures for this subset of women a complete impossibility, just that the only alternative, surgical abortion, presents "significant health risks." *See Gonzales*, 550 U.S. at 161 ("The prohibition in the Act would be unconstitutional, under precedents we here assume to be controlling, if it 'subject[ed] [women] to significant health risks.'") (quoting *Ayotte*, 546 U.S. at 327-28); *see also Casey*, 505 U.S. at 880.

The Supreme Court has repeatedly held that a state may not restrict access to abortions that are "necessary, in appropriate medical judgment, for the preservation of the life or health of the mother." *See Roe*, 410 U.S. at 165; *see also Ayotte*, 546 U.S. at 327-28; *Casey*, 505 U.S. at 879; *see also Gonzales*, 550 U.S. at 161 (quoting *Ayotte*, 546 U.S. at 327-28 (citing *Casey*, 505 U.S. at 879)).

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[21] *See supra* note 17.

This is especially true, as here, when the issue is only previability abortions.

Therefore, the court concludes that the medication-abortion provision of House Bill 2 is an undue burden on those women for whom surgical abortion is, in the sound medical opinion of their treating physician, a significant health risk during the period of pregnancy falling 50 to 63 days LMP.

The medication-abortion provisions do not specifically include an exception for circumstances in which the health of the mother may dictate a particular procedure–here, use of the off-label protocol. "[W]here substantial medical authority supports the proposition that banning a particular abortion procedure could endanger women's health . . . the statute . . . [must] include a health exception when the procedure is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother." *Stenberg*, 530 U.S. at 938 (quoting *Casey*, 505 U.S. at 879) (internal quotation marks and citation omitted). Without such exception, the medication-abortion provisions create an undue burden on the existing right of a woman to an abortion. The legislature appears, however, to have attempted to include a general health-of-the-mother exception applicable to the act as a whole: "this Act does not apply to abortions that are necessary to avert the death or substantial and irreversible physical impairment of a major bodily function of the pregnant woman . . . ." Act of July 12, 2013, 83rd Leg., 2d C.S., ch.1 § 1(4)(B), 2013 Tex. Sess. Law Serv. 4795. The legislature also included a broad severability clause, stating that if "the application of the statute is found to impose an impermissible undue burden on any pregnant woman or group of pregnant women, the application of the statute to those women shall be severed . . . ." Act of July 12, 2013, 83rd Leg., 2d C.S., ch.1 § 1(b), 2013 Tex. Sess. Law Serv. 4795. By the two provisions, the legislature has signaled a clear intent that it will not seek to enforce provisions of the act that a construing court concludes offend the Constitution.

Thus, the court concludes that the medication-abortion provisions do not fail constitutional review because of the lack of a specific health-of-the-mother exception. Rather, the medication-abortion provisions may not be enforced against any physician who determines, in appropriate medical judgment, to perform a medication-abortion using the off-label protocol for the preservation of the life or health of the mother.

CONCLUSION

Based on the above, the court will render a final judgment declaring that the admitting-privileges provision of House Bill 2 does not bear a rational relationship to the legitimate right of the State in preserving and promoting fetal life or a woman's health and, in any event, places a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus and is thus an undue burden to her. The court will enjoin enforcement of that provision. Although the medication-abortion provisions do not generally place an undue burden on a woman seeking an abortion, they do if they ban a medication abortion where a physician determines, in appropriate medical judgment, such a procedure is necessary for the preservation of the life or health of the mother. The court will so declare and enjoin enforcement of those provisions in such instance.

SIGNED this 28th day of October, 2013.

LEE YEAKEL
UNITED STATES DISTRICT JUDGE